

## REMARKS

The Office Action dated July 14, 2004 has been received and carefully studied. Independent claims 1, 3, 5, 6, 8, 9, 13, 17 and 21 have been amended to more particularly point out and distinctly claim the present invention as described below. Reconsideration of the Application by the Examiner is respectfully requested in light of these amendments.

### Rejection Under 35 U.S.C. § 102(e)

The Examiner has rejected claims 13-15, 17-19 and 21-24 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 4,834,747 to Gogolewski. The Examiner contends that Gogolewski discloses the invention identically as recited in the rejected claims. Applicant submits that the claims, as amended, are not anticipated by Gogolewski.

Gogolewski discloses a precipitation method to make a biocompatible soft-tissue prosthesis using a copolymer and a mixed solvent. As described by Gogolewski, the “mixed solvent comprises as a first constituent a fluid which is miscible with the solvent but functions as a precipitating non-solvent with respect to [the] polymer. Furthermore, the mixed solvent comprises a second constituent which is solvent for the polymer.” Col. 1, lines 49-53. In order for Gogolewski’s precipitation method to work, the solvent constituent must have a higher rate of evaporation than the non-solvent constituent, which acts as the precipitating agent. Col. 1, lines 57-59. By applying to the desired prosthetic surface a prepared polymer solution in which the amount of saturated polymer is at or near its precipitation point, Gogolewski teaches that evaporation of the more volatile solvent will cause precipitation of the polymer to form the desired coating the prosthetic surface.

As an example, Gogolewski describes a polymer solvent solution in which THF is the solvent constituent while water is the non-solvent precipitating agent. Col. 2, lines 60-64.

Gogolewski also describes as other suitable solvents DMAc, DMF and DMSO. More importantly, Gogolewski describes the suitable non-solvent precipitating agents as “any fluid having the capacity to precipitate the polymer. A preferred solvent is water but also lower alkanols, such as ethanol, may be used, optionally in combination with water.” Col. 4, lines 10-13 (emphasis added).

Thus, Gogolewski’s method is entirely fluid-based. In contrast, Applicant’s invention teaches an elastomeric shell having a network of interconnected cells resulting from the application of solid particles to an uncured elastomer shell. Following vulcanization of the shell, the solid particles are subsequently dissolved in a solvent leaving an interconnected network of cells varying in size according to the size of the solid particles used. Nowhere does Gogolewski teach, describe or suggest the use of solid particle dissolution as described and claimed by Applicant. The pending independent claims have all been amended to more clearly recite this aspect of the invention.

Because Gogolewski’s fluid precipitant method does not disclose or suggest the claimed invention, Applicant respectfully submits that the rejection of claims 13-15, 17-19 and 21-24 as being anticipated by Gogolewski has been traversed and should be withdrawn.

#### Rejection Under 35 U.S.C. § 103(a)

Claims 1-25 are in the application and stand rejected as obvious under 35 U.S.C. § 103(a) as obvious over Gogolewski in view of U.S. Patent No. 4,648,888 to Brauman. Reconsideration is respectfully requested.

Brauman appears to be cited merely for teaching the use of a rough textured surface in a soft tissue mammary implant. But for the reasons given above, Brauman does not teach or suggest the subject matter of Applicant’s claims as amended, either alone or in

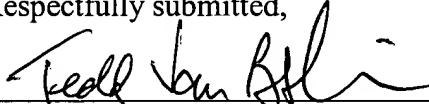
combination with Gogolewski. Therefore, Applicant respectfully submits that claims 1-25, as amended, patentably distinguish over the art of record and respectfully requests an early favorable action on the merits.

### CONCLUSION

Each and every issue raised by the Examiner has been addressed by the above amendments and remarks. Withdrawal of the rejections and reconsideration is respectfully requested. Should the Examiner believe that it would advance the progress of the application, the Examiner is invited to telephone the undersigned at the number below.

Date: January 13, 2005

Respectfully submitted,



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